

DATA EVALUATION RECORD

ACETIC ACID and CITRIC ACID

(SummerSet AllDown Herbicide and SummerSet AllDown Concentrate Herbicide)

STUDY TYPES: Avian Acute Oral Toxicity (OPPTS 850.2100); Avian Dietary Toxicity (OPPTS 850.2200); Non-Target Plant Studies (OPPTS 885.4300); Skin Sensitization (OPPTS 870.2600); Mutagenicity (OPPTS 870.5100); Immune Response (OPPTS 880.3550); Acute Inhalation Toxicity (OPPTS 870.1300)

MRIDs 47330504 and 47330508

Prepared for
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Task Order No. 08-024

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DATA EVALUATION RECORD

EPA Secondary Reviewer: Angela L. Gonzales 1/21/10 /s/ 

STUDY TYPE: Information to Support and/or Waive Data Requirements

MRID NOs: 47330504 and 47330508

DECISION NO: 389083

DP BARCODE: DP352241

TEST MATERIAL: SummerSet AllDown Herbicide (a.i 8% acetic acid, 6% citric acid) and SummerSet AllDown Concentrate Herbicide (a.i. 23% acetic acid, 14% citric acid)

PROJECT STUDY NO: MRID 47330504: None provided
MRID 47330508: None provided

SPONSOR: SummerSet Products, 130 Columbia Court, Shaska, MN 55318

TESTING FACILITY: N/A

TITLE OF REPORT: MRID 47330504: Data Waiver Request for Acetic Acid, Technical Grade Active Ingredient
MRID 47330508: Data Waiver Request for Citric Acid, Technical Grade Active Ingredient

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STUDY COMPLETED: MRID 47330504: January 14, 2008
MRID 47330508: January 14, 2008

CONFIDENTIALITY CLAIMS MRID 47330504: None
MRID 47330508: None

GOOD LABORATORY PRACTICE: MRID 47330504: A signed and dated GLP statement was included. The document is a presentation of factual material and is not subject to GLP requirements.
MRID 47330508: A signed and dated GLP statement was included. The document is a presentation of factual material and is not subject to GLP requirements.

CONCLUSION: The petitioner has submitted information and rationale to support and/or waive certain data requirements for the active ingredients for SummerSet AllDown Herbicide and SummerSet AllDown Herbicide Concentrate for the following requirements: Avian Acute Oral Toxicity (OPPTS 850.2100); Avian Dietary Toxicity (OPPTS 850.2200); Non-Target Plant Studies (OPPTS 885.4300); Acute Inhalation Toxicity (OPPTS 870.1300) (citric acid only); Sensitization (OPPTS 870.2600); Mutagenicity (OPPTS 870.5100); and Immune Response (OPPTS 880.3550). The information submitted is sufficient to support and/or waive each of these data requirements.

Product Description

SummerSet AllDown Herbicide "Ready to use" (a.i. 8% acetic acid and 6% citric acid) and SummerSet AllDown Concentrate Herbicide (a.i. 23% acetic acid and 14% citric acid) are end-use products to be used as non-selective herbicides for broadleaf and grass weeds. They are applied as a foliage spray to weeds 3-5 inches high. The inert ingredients in SummerSet AllDown Herbicide are [REDACTED] The inert ingredients in SummerSet AllDown Concentrate Herbicide are [REDACTED]

Information to Support and/or Waive Data Requirements

The registrant has submitted information regarding the following data requirements for the TGAIs acetic acid and citric acid and for the formulated end use products: SummerSet AllDown Herbicide and SummerSet AllDown Concentrate Herbicide.

Waivers Requested for Acetic Acid and Citric Acid	
Acetic Acid	Citric Acid
Skin Sensitization (OPPTS 870.2600)	Skin Sensitization (OPPTS 870.2600)
Mutagenicity (OPPTS 870.5100)	Mutagenicity (OPPTS 870.5100)
Immune Response (OPPTS 880.3550)	Immune Response (OPPTS 880.3550)
Avian Acute Oral Toxicity (OPPTS 850.2100)	Acute Inhalation Toxicity (OPPTS 870.1300)
Avian Dietary Toxicity (OPPTS 850.2200)	Avian Acute Oral Toxicity (OPPTS 850.2100)
Non-Target Plant Studies (OPPTS 885.4300)	Avian Dietary Toxicity (OPPTS 850.2200)
	Non-Target Plant Studies (OPPTS 885.4300)

REGISTRANT'S JUSTIFICATION

General

Acetic acid is a commonly consumed food commodity. It is eaten as vinegar in salad dressing and other food products such as condiments at levels up to 9.0% (21 CFR 181.1005). It is also a list 4B inert and exempted from the requirement of a tolerance when applied to growing crops pre- and post-harvest per 40 CFR 180.910. Acetic acid as an a.i. has a tolerance exemption on hay and stored grain.

Citric acid is a commonly consumed food commodity, occurring naturally in fruits and as an added flavoring or preservative. It is a part of natural metabolic processes in plants and animals.

The Reregistration Eligibility Document for Citric Acid waived the generic data requirements for toxicology, human exposure, ecological effect, and environmental fate for the active ingredient.

Skin Sensitization

Acetic Acid

Concentrated acetic acid applied to skin will cause irritation and can cause burns. In concentrated form it has a pH of 2.2 and is an eye irritant and irritant of the mucous membranes of nose, larynx, esophagus, and lungs. Lewis (1992) did not specifically list acetic acid as a dermal sensitizer. Acetic acid is a normal part of metabolic cycles. Under 40 CFR 158.690 skin sensitization for terrestrial non-food use is a conditional requirement. There is a long history of use of acetic acid without reports of skin sensitization.

Citric Acid

Citric acid (0.1N solution) applied to skin will cause irritation and can cause burns. In concentrated form it has a pH of 2.2 and is an eye irritant and irritant of the mucous membranes of nose, larynx, esophagus, and lungs. The NIOSH safety card reports skin redness as a result of exposure. Citric acid is a normal part of metabolic cycles. Under 40 CFR 158.690 skin sensitization for terrestrial non-food use is a conditional requirement. There is a long history of

use of citric acid without reports of skin sensitization. In the formulation process, exposure to granular citric acid is reduced by the use of protective clothing and eyewear.

Reviewer's Comments: Toxicity data on the proposed EPs containing both active ingredients indicate that the products are not dermal sensitizers. Additionally, precautionary statements on the label reduce the likelihood of repeated skin contact.

Mutagenicity

Acetic Acid

No genetic toxicity was noted in the Ames test and acetic acid with or without S9 activation at levels of 100 to 10000 µg per plate (USEPA 2007).

Citric Acid

No genetic toxicity was noted in the Ames Test with citric acid with or without S9 activation at levels of 2000 µg/plate (USEPA 2007). In male rats treated with citric acid up to 3 kg/kg/day for 5 days, the dominant lethal assay was negative. No chromosomal damage occurred in the bone marrow cells of these male rats (USEPA 2007).

Reviewer's Comments: The reviewer's search of HSDB revealed additional test results. No chromosomal aberrations were observed in Chinese hamster ovary (CHO) cells and Chinese hamster fibroblast cells tested with acetic acid and acetic acid sodium salt. Clastogenicity of acetic acid in CHO cells is related to the change in pH (general acidity) of the test medium. Neutralization of the acid resulted in loss of clastogenic effects of acetic acid. No clastogenic effects were seen in Chinese hamster fibroblasts treated with 1 mg/ml of citric acid. Given the widespread use and consumption of citric acid, no chromosomal defects have been previously reported.

Immune Response

Acetic Acid: Acetic acid has a long history of food-use applications and is widely used in pesticide products. Extensive use and manufacturing information is available. Acetic acid is endogenously formed as part of normal metabolic processes.

Citric Acid: Citric acid has a long history of food-use applications and is widely used in antimicrobial and pesticide products. Extensive use and manufacturing information is available.

Citric acid is formed endogenously as a part of normal metabolic processes. Additional exposure is expected to be minimal from the proposed new use. No specific data was found on other immune system responses or adverse effects.

Reviewer's Comments: The reviewer's search of HSDB found reported hypertrophy of lymph nodes in workers chronically exposed to concentrations up to 200 ppm acetic acid. A maintenance worker exposed to glacial acetic acid was diagnosed with interstitial pneumonia with a doubling in macrophages and ten-fold increase in lymphocytes in the affected lung tissue. There is one reported study of an anaphylactic response to vinegar and acetic acid and positive responses to low concentration skin pin-prick studies (HSDB). HSDB also reports that guinea pig mast cells showed increased histamine release with 3 mg/ml dose.

Acute Inhalation (citric acid)

The source of citric acid in the proposed EPs is not likely to be respirable as it exists in granular form. Should any dust be generated, there is the potential for respiratory congestion if inhaled. Inhalation toxicity testing on both of the proposed EPs indicates low toxicity as well (Toxicity Category IV).

Avian Acute Oral and Avian Dietary Toxicity

Acetic Acid: Acetic acid is corrosive and damage to mammals has reported esophageal damage during testing. It is not necessary to conduct an avian toxicity study using a corrosive test material. In the open environment, acetic acid is aerobically degraded showing a 99% degradation in seven days.

Citric Acid: Citric acid is a natural metabolite. HSDB does not list adverse avian effects. In the open environment, citric acid is quickly degraded with 98% degradation in 48 hours (USEPA, 2008). Citric acid is naturally found in fruits consumed by certain avian species. The RED for citric acid stated that it is unlikely that citric acid poses a significant risk to the environment.

Reviewer's Comments: HSDB does not list adverse avian effects for acetic acid. It is possible that acetic acid will result in a taste aversion to avian food sources after use. Environmental levels of citric acid remaining on avian food sources will rapidly degrade in the environment.

Non-Target Plant Studies

Acetic Acid: The product is designed as a non-specific herbicide. Application of the product will impact plant vigor. Toxicity to algae was observed at 4000 mg/l (USEPA 2007).

Citric Acid: No specific studies on the effects of citric acid on seedling germination or vegetative vigor. Toxicity to aquatic plants was 640 mg/l (72-hour EC₅₀) (USEPA 2007). Plants naturally produce citric acid in energy metabolic cycles. The RED for citric acid stated that it is unlikely that citric acid poses a significant risk to the environment.

Reviewer's Comments: Specific label instructions direct users to avoid spraying desirable foliage. Specific label instructions preclude direct application to water. The reviewer's search of HSDB found results of acetic acid fumigation testing on corn, soybean, tobacco, wheat, alfalfa. Leaf injury was reported in all plants at concentrations from 8 to 50 mg/m³/2-hour exposure. Specific label instructions direct users to avoid spraying desirable foliage. Specific label instructions preclude direct application to water.

References

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